REMARKS

Claims 1-18, 21-30 are canceled; claims 19-20 and 31 are amended; and claims 32-54 are added herein. Support for the amendments to the claims and the new claims is found, for example, in the original claims and the specification on page 6, lines 17-21, page 6, line 26 to page 7, line 2, page 7, lines 8-17 and lines 21-24, and page 8, lines 3-5. Hence no issues of new matter are presented. Accordingly, upon entry of the Amendment, claims 19-20 and 31-54 will be all of the claims pending.

I. Objections to Specification

The specification is objected to under 35 U.S.C. § 132 as containing new matter. It is the Examiner's position that the term "flavoring agents" is new matter because it was not disclosed nor recited in the originally filed specification or claims. The Examiner states that Applicants are required to cancel the new matter in reply to the Office Action.

Applicants submit that the original term "corrective agents" was an inaccurate translation. To correct this translation error, copies of the relevant pages of the Japanese language PCT application no. PCT/JP98/04374 and a declaration indicating that "corrective agents" was an inaccurate translation and that "flavoring agents" is the correct translation are submitted herewith. Since the PCT application was the original application, the PCT application can be relied on to correct an error in the present application, which is supposed to be simply a translation of the PCT application per MPEP 1893.01(d).

Accordingly, Applicants respectfully request withdrawal of the objection to the specification.

II. Claim Rejections Under 35 U.S.C. § 112, 1st paragraph

Claims 16 and 20 are rejected under 35 U.S.C. § 112, 1st paragraph as allegedly containing new matter because of the recitation, "flavoring agents". The Examiner states that Applicants are required to cancel the new matter recited in the claims in response to the Office Action.

Applicants respectfully traverse the rejection as to claim 20 and submit that the term "flavoring agents" is the correct translation of the original PCT application as indicated in the attached Declaration and copies of the relevant pages of the PCT application, and as discussed above. Claim 16 is canceled herein and therefore the rejection as to claim 16 is moot.

Accordingly, Applicants respectfully request withdrawal of the rejection.

Claims 1 and 3-20 are rejected under 35 U.S.C. § 112, 1st paragraph as allegedly being non-enabled for drugs with at least one basic group in its structure thereby rendering an unpleasant taste, essentially for the reasons of record. It is the Examiner's position that there is no adequate direction provided in the specification as to how to select other unpleasant tasting drugs with at least one basic group in its structure which would be suitable to practice the invention. As an example the Examiner refers to aspartame, which is said to contain a basic amino group, but which is known to be useful as a sweetener, and according to the Examiner does not have an unpleasant taste.

Applicants respectfully traverse the rejection as to claims 19 and 20 and submit that the present claims as amended are sufficiently enabled by the original specification and that it would not require undue experimentation by one of ordinary skill in the art to practice the claimed

invention. Claims 1 and 3-18 are canceled herein and therefore the rejection as to these claims is rendered moot.

Accordingly, Applicants respectfully request withdrawal of the rejection.

III. Claim Rejection Under 35 U.S.C. § 112, 2nd paragraph

Claims 1, 3-20, 29, 30 and 31 are rejected under 35 U.S.C. § 112, 2nd paragraph as allegedly being indefinite, essentially for the reasons of record, with respect to the terms "unpleasant taste" and "bitter taste". In addition the Examiner states the phrase "crude drug selected from . . ." in claim 30 renders the claim indefinite as to what active compounds are encompassed by the claim. Further, the Examiner states that there are many active ingredients in herbal products and it is not clear what compounds would be considered as "crude drugs".

Applicants respectfully traverse the rejection as to claims 19, 20 and 31, and submit that the claims as amended are definite in view of the drugs recited therein, and particularly when properly read in light of the specification. Claims 1, 3-18, 29 and 30 are canceled herein and therefore the rejection as to these claims is moot.

Accordingly, Applicants respectfully request withdrawal of the rejection.

IV. Claim Rejections Under 35 U.S.C. § 102

A. Pearmain

Claims 1, 3-7, 9, 12-14 and 16-18 are rejected under 35 U.S.C. § 102(b) over Pearmain for the reasons of record. On pages 9-11, the Examiner responds to the arguments previously made. Basically, it is the Examiner's position that it is Applicants' burden to establish that the additional polymethacrylate material of Pearmain would affect the basic and novel characteristics of the claimed invention.

Claims 1-18 are canceled herein and therefore the rejection is moot. Pearmain does not specifically disclose erythritol, which is specifically recited in the present claims as amended. In view thereof, Pearmain does not teach all elements of the claimed invention and therefore does not anticipate the claims.

Accordingly, Applicants respectfully request withdrawal of the rejection.

B. Behrakis et al

Claims 1 and 26 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Behrakis et al, which is said to disclose an oral theophylline pharmaceutical composition consisting essentially of theophylline, sorbitol, a sugar alcohol, and a pH adjusting agent, namely citric acid.

Claims 1 and 26 are canceled herein and therefore the rejection is moot. Behrakis et al does not specifically teach a drug or erythritol as recited in the present claims and therefore Behrakis et al does not anticipate the presently claimed invention.

Accordingly, Applicants respectfully request withdrawal of the rejection.

C. Breillat, Jr., et al.

Claims 1 and 27 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Breillat, Jr. et al, which is said to disclose an ampicillin oral composition consisting essentially of sorbitol, ampicillin and sodium bicarbonate, a pH adjusting agent.

Claims 1 and 27 are canceled herein and therefore the rejection is rendered moot. Breillat, Jr., et al. does not specifically teach a drug or erythritol as recited in the present claims and therefore Breillat, Jr., et al does not anticipate the claimed invention.

Accordingly, Applicants respectfully request withdrawal of the rejection.

D. Mercer et al

Claims 1, 26, 29 and 30 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Mercer et al, which is said to teach an oral composition consisting essentially of sorbitol, ephedrine hydrochloride, theophylline and citric acid.

Claims 1, 26, 29 and 30 are canceled herein and therefore the rejection is moot. Mercer et al does not specifically teach a drug or erythritol as recited in the present claims and therefore, Mercer et al does not anticipate the claimed invention.

Accordingly, Applicants respectfully request withdrawal of the rejection.

V. Claim Rejections Under 35 U.S.C. § 103

Claims 8, 10-11, 15, 19, 20, 28, and 31 are rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Pearmain in view of Hoshino for the reasons of record. On pages 13-14 the Examiner responds to the arguments previously made. The Examiner states that the argument that Hoshino fails to teach the improvement of the unpleasant taste of drugs is irrelevant in view of the grounds for rejection. The Examiner states that the rejection is not based on whether sucralfate has an unpleasant taste or not. Further, the Examiner states that the instant claims are drawn to a composition and that all of the characteristics or properties of the product are not given patentable weight.

Claims 8, 10-11, 15 and 28 are canceled herein and therefore the rejection is rendered moot as to these claims. As to claims 19 and 31, Applicants respectfully traverse the rejection and submit that the cited references, taken alone or in combination, do not teach or suggest the presently claimed invention.

Hoshino discloses that the gastrointestinal drug ingredient can be conveniently taken while overcoming the problem of the undesirable texture in the mouth, which is characteristic of the drug ingredient. As previously discussed, Hoshino relates to a technique for improving intrabuccal sensations (discomfort such as roughness or dustiness) that is characteristic of chewable tablets containing a gastrointestinal drug. Thus, Hoshino's technique is quite different from the method for improving an unpleasant taste of a drug using erythritol as in the claimed invention.

The present invention is directed to improving the unpleasant taste of drugs to such a degree that the unpleasant tastes are reduced or completely undetectable with respect to oral administration preparations of drugs having unpleasant tastes that are completely or partially dissolved in the oral cavity before swallowing them.

On the other hand, Pearmain discloses a technique directed to a palatable granule comprising cimetidine, which is prepared by granulating cimetidine with a particular amount of a particular polymethacrylate copolymer. That is the technique disclosed by Pearmain is to improve palatability.

Thus, one of ordinary skill in the art would not have been motivated to combine the teachings of Pearmain directed to the improvement of palatability (which is entirely different from the claimed method of improving the unpleasant taste of drugs) and Hoshino which is directed to the improvement of the undesirable texture of a gastrointestinal drug with a reasonable expectation of success in achieving the claimed invention.

Accordingly, Applicants respectfully request withdrawal of the rejection.

VI. Request for an Interview with the Examiner

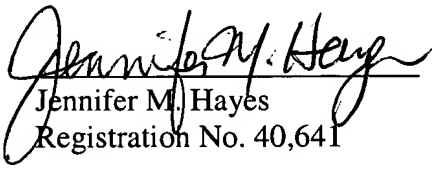
Applicants respectfully request an interview with the Examiner to discuss the application further in view of the amendments to the claims and arguments made herein. The Examiner is kindly requested to contact the undersigned at (202) 775-7533 to schedule a time for an interview.

VII. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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23373
CUSTOMER NUMBER

Date: July 29, 2003